NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CAROL HERBERT, et al., Plaintiffs, v. MENTOR, et al., Defendants.	CIVIL ACTION NO. 04-413 (MLC) **MEMORANDUM OPINION**

COOPER, District Judge

Plaintiffs, Carol Herbert and Glenn Herbert (collectively, "plaintiffs"), allege claims of state-law products liability based on strict liability, negligence, and breach of warranty.[1] (Dkt. entry no. 1, Notice of Removal, Ex. A, Compl.) Defendant moves for summary judgment in its favor pursuant to Federal Rule of Civil Procedure ("Rule") 56(c). (Dkt. entry no. 19.) The Court, for the reasons stated herein, will grant the motion for summary judgment.

BACKGROUND

The products at issue here are Mentor Style 1400 Round Smooth Spectrum ("1400 Round") breast implants, that are saline-filled with silicone shells. (Dkt. entry no. 20, Def. Statement of Undisputed Material Facts ("Def. Facts"), at ¶ 9.) Under 21 C.F.R. § 878.5730, the 1400 Round breast implant is classified as

[1] The complaint lists Mentor and Mentor, Inc. as defendants. However, the sole true defendant is Mentor Corporation. (See dkt. entry no. 19, Notice of Motion.) The Court, therefore, will refer to "defendant" in this memorandum opinion.

a Class III medical device. (Id. at ¶ 4.) Class III medical devices are regulated by the Medical Device Amendments, 21 U.S.C. § 360, et seq., to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (Id. at ¶ 5.) As a Class III medical device, the 1400 Round required pre-market approval ("PMA") by the Federal Food and Drug Administration ("FDA") before it could be distributed commercially to healthcare professionals. (Id. at ¶ 6.)

Defendant submitted a PMA application to the FDA on November 12, 1999, for breast implants, including the 1400 Round. (Id. at ¶ 9.) This application included detailed information pertaining to the design, manufacturing process, and labeling of the 1400 Round. (Id.) On May 10, 2000, defendant received a PMA order for the 1400 Round from the FDA, permitting it to be sold to healthcare professionals. (Id. at ¶ 10; see also dkt. entry no. 26, Def. Reply, Ex. A, 1400 Round's PMA Order ("PMA Order").) Thereafter, the 1400 Round could only be sold in accordance with the specifications approved by the FDA in the PMA. (Def. Facts, at ¶ 10.) The two 1400 Round breast implants at issue here were manufactured according to these specifications. (Id. at ¶ 11.)

Plaintiff Carol Herbert was diagnosed in 2000 with breast cancer in her right breast, and had surgery to undergo a bilateral mastectomy and insert tissue expanders, manufactured by

defendant, into her body. (Compl., Count 1, at ¶ 2.)[2] The left breast mastectomy was prophylactic. (Id.) In January 2001, plaintiff Carol Herbert had bilateral breast implants inserted into her body. (Id., Count 1, at ¶ 3.) Both breast implants were 1400 Round breast implants manufactured by defendant. (Id.; Def. Facts, at ¶ 1.) In January 2002, she underwent surgery to remove the left breast implant because it deflated. (Compl., Count 1, at ¶ 4.) During the same surgery, a second 1400 Round left breast implant, also manufactured by defendant, was inserted into her body. (Id., Count 1, at ¶¶ 4, 5.) In April 2002, the second left breast implant deflated, and she underwent surgery to remove that breast implant. (Id., Count 1, at ¶ 5.)

Plaintiffs commenced this action in New Jersey Superior Court, Mercer County against defendant in December 2003. (See id.) The complaint alleges claims of products liability under state law based on strict liability, negligence, and breach of warranty. (Id., Count 1, at ¶ 7; Count 2, at ¶ 2.) Plaintiff Glenn Herbert additionally alleges a derivative claim. (Id., Count 2, at ¶ 2.) On February 2, 2004, defendant removed this

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[2] Plaintiffs, in their Counter-Statement of Contested Facts ("Counter-Statement"), state plaintiff Carol Herbert's diagnosis of breast cancer occurred in April 2000, and the bilateral mastectomy and insertion of the tissue expanders occurred on May 25, 2000. (Dkt. entry no. 23, Counter-Statement, at ¶ 1.) But the complaint asserts her diagnosis of breast cancer, bilateral mastectomy, and insertion of tissue expanders occurred on January 24, 2000. (Compl., at ¶ 2.) For the purposes of this memorandum opinion, this contradiction is irrelevant.

action to this Court on the basis of jurisdiction under 28 U.S.C. § 1332. (Notice of Removal.) Defendant now moves for summary judgment in its favor. (Dkt. entry no. 19.) Defendant asserts that plaintiffs' claims are preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. (Dkt. entry no. 20, Def. Br., at 2.)

DISCUSSION

I. Standard of Review for Summary Judgment

Rule 56(c) provides that summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The party moving for summary judgment bears the initial burden of showing that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the movant has met this prima facie burden, the non-movant "must set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). A non-movant must present actual evidence that raises a genuine issue of material fact and may not rely on mere allegations. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

The Court must view the evidence in the light most favorable to the non-movant when deciding a summary judgment motion.

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). At the summary judgment stage, the Court's role is "not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson, 477 U.S. at 249. Under this standard, the "mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient [to defeat a Rule 56(c) motion]; there must be evidence on which the jury could reasonably find for the [non-movant]." Id. at 252. "By its very terms, this standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Id. at 247-48 (emphasis in original). A fact is material only if it might affect the action's outcome under governing law. Id. at 248. "[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Id. at 249-50 (internal citations omitted).

II. Federal Preemption under the Medical Device Amendments

A. The Medical Device Amendments

The Medical Device Amendments classify medical devices into three categories. See 21 U.S.C. § 360c(a). Class I devices are

subject to less stringent "general controls" because they are "not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," and they do not "present a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(A). Class II devices are subject to "special controls" because "the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(B). "Special controls" may include "promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines . . . recommendations, and other appropriate action as . . . deem[ed] necessary to provide such assurance." Id.

Class III devices are subject to PMA from the FDA "to provide reasonable assurance of [their] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). This is because such devices are either "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presen[t] a potential unreasonable risk of illness or injury." Id. Silicone breast implants are Class III devices. 21 C.F.R. § 878.3530.

There is a process in place for obtaining PMA from the FDA. See 21 U.S.C. § 360e(c),(d); Medtronic, Inc. v. Lohr, 518 U.S.

470, 477 (1996). "[M]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." Lohr, 518 U.S. at 477. Further, once a Class III device receives a PMA order from the FDA, the FDA retains continuing oversight over that device. See, e.g., 21 U.S.C. § 360e(e); 21 C.F.R. §§ 814.80, 814.82. For example, a device may not be manufactured in any way that is inconsistent with its PMA order; the specifications approved by the FDA in the PMA order must be adhered to by the manufacturer. 21 C.F.R. § 814.80. Also, the FDA may impose post-approval requirements as conditions to the approval of the device. 21 C.F.R. § 814.82. Further, the FDA may withdraw or temporarily suspend the PMA. See 21 U.S.C. § 360e(e).

The Medical Device Amendments also contain an express preemption provision. See 21 U.S.C. § 360k(a). This provision provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

B. Plaintiffs' Strict Liability, Negligence and Breach of Implied Warranty Claims

The Third Circuit has interpreted the extent to which Section 360k(a) preempts state law claims in the context of a Class III medical device that received a PMA order from the FDA. See Horn v. Thoratec Corp., 376 F.3d 163, 164-77 (3d Cir. 2004); Michael v. Shiley, Inc., 46 F.3d 1316, 1320-28 (3d Cir. 1995). In Horn, the court held that the plaintiff's claims of negligence, breach of implied warranty, and strict liability were expressly preempted by Section 360k(a). See 376 F.3d at 179-80. Because the device's design, labeling, and other specifications approved by the PMA order created specific federal requirements applicable to the device, "any finding in [plaintiff's] favor based on her general claims of negligence or defective design and manufacture . . . would necessarily amount to a state substantive requirement 'different from, or in addition to, the federal requirements imposed by the FDA.'" Id. at 179. Moreover, the plaintiff did not assert that the defendant either failed to conform with the FDA requirements prescribed by its PMA order, or violated any federal statutes or FDA regulations. Id. None of plaintiff's claims therefore could avoid preemption. Id. at 179-80.

The court in Horn also distinguished the Lohr decision in reaching its decision. Id. at 168. In Lohr, a plurality of the Court held that the plaintiff's state product liability claims against a defendant manufacturer of a Class III device were not

preempted. Lohr, 518 U.S. at 494-501. The Horn court noted that the Lohr plurality opinion concerned a Class III device, a pacemaker, that was given FDA approval under the 21 U.S.C. § 501(k) "substantial equivalence" process, which imposes generic federal standards on a device, as opposed to specific requirements. Horn, 376 F.3d at 168. The Court in Lohr, as a result, did not consider whether the more rigorous PMA process under 21 U.S.C. § 360e(c) constituted a specific federal regulation of the device, as it imposed strict FDA requirements upon the manufacturer. Id.

Plaintiffs' claims here are preempted by Section 360k(a) because the Horn decision is dispositive. First, as in Horn, the 1400 Round breast implant is a Class III medical device, which has received a PMA order from the FDA. Second, the PMA process in this case, as for the device in Horn, imposed federal requirements that were specifically applicable to the 1400 Round breast implants. (Def. Facts, at ¶ 11.) These requirements included specifications applicable to the design of the silicone shells and the manufacturing processes used to make the silicone shells. (Id.) Also, the 1400 Round breast implants' labeling specifications were also approved by the FDA.[3] Third, plaintiffs

[3] The PMA Order states that "[y]ou are reminded that, as soon as possible, you must submit an amendment to this PMA submission with copies of the approved patient labeling (i.e., patient informed decision brochure) and package labeling in final printed form.")

here also allege only state-law imposed product liability claims that attack as defective the same specifications approved by the FDA.[4] (Compl., Count 1, at ¶ 7.) Plaintiffs do not allege any violations of the PMA Order, or any other federal statutes or FDA regulations. (See Compl.) Thus, as in Horn, any finding in the plaintiffs' favor would amount to a state requirement "different from, or in addition to, the federal requirements imposed by the FDA." Horn, 376 F.3d at 179. None of plaintiffs' claims can avoid preemption under Section 360k(a).

Plaintiffs' argument that preemption does not apply here because the defendant's device only received "conditional" approval in the PMA Order, and thus has not been approved as safe and effective, is unavailing. (Dkt. entry no. 24, Pl. Br., at 15-18.) As discussed supra, the FDA retains continuing oversight over the approved device in a variety of ways, including imposing conditions to a PMA order. See, e.g., 21 U.S.C. § 360e(e); 21 C.F.R. §§ 814.80, 814.82. This does not mean, however, a device is not approved as safe and effective by the FDA; if the FDA so chose, it could withdraw a device's PMA order if it found the device was no longer safe and effective. See 21 U.S.C. § 360e(e). Further, even the device in Horn had conditions attached to its PMA order. See Horn v. Thermo Cardiosystems,

[4] Under New Jersey state law, products liability is governed by statute, N.J.S.A. § 2A:58C-1, et seq., as well as common law.

Inc., 229 F.Supp.2d 381, 387-88 (M.D. Pa. 2002) ("[A]fter 2.5 years of review of the PMA application, the FDA approved the HeartMate for commercial sale. The FDA stated that TCI [Thermo Cardiosystems, Inc.] was required to comply with a series of conditions"), aff'd sub nom., Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004).

C. Plaintiffs' Breach of Express Warranty Claim

Plaintiffs also argue that they have a claim based upon breach of express warranty under state law. (Pl. Br., at 18.) Plaintiffs point to defendant's two types of limited "warranties" for the 1400 Round breast implants, both of which include, inter alia, a "lifetime product replacement policy" and financial assistance for various surgical costs.[5] (Counter-Statement, Ex. B.)

The Third Circuit has held that a breach of express warranty claim is not subject to preemption under 21 U.S.C. § 360k(a). Michael, 46 F.3d at 1325. The court in that case distinguished an express warranty from an implied warranty, where the parties to a contract define the substantive obligations of the contract, and the state merely enforces those obligations. Id.; see Horn,

[5] It should be noted that the brochure plaintiffs use as evidence of the "warranties," and which is aimed at patients who are the consumers of the defendant's breast implants, explicitly provides: "This is a summary of Mentor's Standard and Enhanced Advantage coverages. It is an overview only and not a complete statement of the program." (Counter-Statement, Ex. B.)

376 F.3d at 168 n.7. As the preemption provision only preempts state imposed, not state enforced requirements, the court held that the plaintiff's breach of express warranty claim was not preempted. Id.

Plaintiffs, however, cannot prevail on this claim. They did not allege it in the complaint. (See Compl.) The only language used in the complaint pertaining to breach of warranty is an allegation of breach of an implied warranty. (Id., Count 1, at ¶ 7 ("The adjustable mammary protheses . . . were not fit, suitable and safe for the uses and purposes intended . . .").) See N.J.S.A. § 12A:2-314(2)(c) ("Goods to be merchantable must be at least such as . . . (c) are fit for the ordinary purposes for which such goods are used . . .") Further, plaintiffs may not amend the complaint to add such a claim to their allegations in their briefs in opposition to the motion for summary judgment. See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc., 482 F.3d 247, 252-53 (3d Cir. 2007) ("[T]o request leave to amend a complaint, the plaintiff must submit a draft amended complaint to the court so that it can determine whether amendment would be futile."); Ranke v. Sanofi-Synthelabo, Inc., 436 F.3d 197, 206 (3d Cir. 2006) (noting the district court was correct in not granting leave to amend the complaint when the appellants' "request" to amend only appeared in their response to a motion to dismiss, because "[i]f appellants had been in possession of facts

that would have augmented their complaint and possibly avoided dismissal, they should have pled those facts in the first instance. They failed to do so."). Plaintiffs, therefore, cannot prevail on their argument that a breach of express warranty occurred here.

Even if plaintiffs had properly pled a breach of express warranty, such a claim would not prevail here. Under New Jersey law, an express warranty is formed when representations, in the form of any affirmation of fact or promise, description of the good, or use of a sample or model, made by the seller become a "part of the basis of the bargain" between the consumer and seller. N.J.S.A. § 12A:2-313(1). Representations become a part of the basis of the bargain "once the buyer has become aware of the affirmation of fact or promise." Liberty Lincoln-Mercury, Inc. v. Ford Motor Co., 171 F.3d 818, 825 (3d Cir. 1999). The focus of the inquiry is on "whether the seller's actions or language when viewed in light of his relationship with the buyer were fairly regarded as part of the contract to purchase the good." Id. Plaintiffs here were neither aware of nor knew of defendant's limited "warranties." (Dkt. entry no. 26, Def. Reply Br., Ex. C.) As such, the "warranties" did not become a "part of the basis of the bargain," and it cannot be said that they were "part of the contract to purchase the good." See Liberty Lincoln-Mercury, Inc., 171 F.3d at 825.

CONCLUSION

The Court, for the reasons stated supra, will grant the motion for summary judgment. The Court will issue an appropriate order and judgment.[6]

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

[6] Defendant also separately moved to exclude plaintiffs' expert, James Pugh, Ph.D, and to strike Exhibit J to plaintiffs' Counter-Statement. (Dkt. entry nos. 21 & 27.) These separate motions, in light of the Court's disposition of the motion for summary judgment, will be denied as moot.